

REMARKS

Claims 1, 3-8, 11, 12, 21 and 22 have been amended to more distinctly claim the invention. Claims 24-28 have been added to claim an immunoassay method utilizing the claimed antibodies as set forth in the specification, for example at [0024], [0047], [0055], and [0057]. It is believed that none of these amendments constitute new matter and their entry is requested.

In the Office Action mailed July 16, 2004, the Examiner restricted the claims into Groups I-III. Applicants provisionally elect the claims of Group I. As a species of peptide, Applicant elects the peptide Phe-Gly-Leu-Met-NH₂ set forth in SEQ ID NO:2. Claims 1-2, 7-8, 9-17, 21-23, and new claims 24-28 read thereon. This election is made with traverse.

There are two criteria for a proper requirement for restriction between patentably distinct inventions: 1) The inventions must be independent or distinct as claimed; and 2) There must be a serious burden on the Examiner if restriction is not required. See MPEP § 803. Examiners must provide reasons and/or examples to support conclusions. For purposes of the initial requirement, a serious burden on the Examiner may be *prima facie* shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant.

In the restriction requirement, the Examiner has identified Groups I-III as: claims 1-10 are drawn to an antibody that specifically binds a peptide sequence; claims 11-17 are drawn to a method of detecting magnesium binding defect; and claims 21-23 are drawn to a method of monitoring the progress of treatment of magnesium binding defect.

The Examiner has stated in his restriction between Group I and Groups (II and III), that these inventions are related as product and process of use. In the restriction requirement, the Examiner asserted that the antibody of Group I could be used for western blotting rather than the methods of Groups II and III. Applicant disagrees with this assertion and traverses the restriction between Group I and Groups (II and III). As emphasized in the specification, methods for the diagnosis and treatment of disorders associated with magnesium binding include any appropriate method that permits the determination of the blood plasma levels of the peptides. [0025] It is further stated in the application that a preferred embodiment of the invention employs immunochemical procedures (i.e., “binding assays”) to detect the occurrence of the magnesium binding effect, and that the invention involves binding assays wherein a binding pair member having affinity to one or more of the peptides is employed to detect the amount(s), presence or absence of the peptide(s) in question. [0026] In accordance with the invention as described in the specification, the independent claims of Groups II and III are not restricted to any particular immunoassay method; any appropriate diagnostic/screening assay may be utilized. Such assays do not materially differ in that each is a binding assay using a binding pair, having an affinity to one or more of the peptides. As such, the antibodies of Group I may optionally be utilized in a western blotting assay according to the invention of independent claims 11 and 21. Use of western blotting as a qualitative and quantitative assay is exemplified in Tapprich and Dahlberg, EMBO J. 9:2649-2655 (1990). Thus it is submitted the Examiner’s restriction between the antibodies of Group I and the assays of Groups II and III is improper.

Applicant further traverses the requirement for restriction between Groups II and III. Applicant agrees that the claims of Groups II and III are directed to different methods. However, as stated in the MPEP and discussed above, distinctness alone is not enough to require

restriction. It is urged that the burden of examining the methods of the present application is not a serious one. The method steps recited in Group II and III are very similar in that they both involve measuring the level of one or more of the peptides, followed by comparing the measured levels to a standard (in Claim 21, the measured level of step a) is used as the “standard” for comparison). Accordingly, it imposes no serious additional burden upon the Patent Office to search the methods claims as one group for examination.

Concerning the requirement for election of a single disclosed species for prosecution on the merits, each of claims 1-2, 9-17, 21-23, and new claims 24-28, are drawn to a Markush group of three peptides. Applicant agrees that these peptides are distinct from each other. However, as stated in the MPEP and discussed above, distinctness alone is not enough to require a restriction. There must also be a serious burden upon the Examiner. In so far as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria are set forth in MPEP § 803.02. See MPEP § 803. If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the Examiner will not require restriction. See MPEP § 803.02. Thus, it is urged that the burden of examining the three peptides of the present application is not a serious one, and that the burden of examining all three peptides is the same as examining one of the peptides of the identified claims.

In view of the above arguments, it is requested that the restriction requirement imposed in the Office Action mailed July 16, 2004, be reconsidered and that all of the claims be properly examined together, and further that the Markush group of peptides be examined together.

Respectfully submitted,

By:



Nancy T. Morris, Reg. No. 42,017
STINSON MORRISON HECKER LLP
1201 Walnut Street, Suite 2800
Kansas City, MO 64106-2150
Telephone: (816) 842-8600
Facsimile: (816) 691-3495
Attorney for Applicant(s)